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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,541	04/13/2001	Kengo Akimoto	001560-396	7683

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EXAMINER

SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/807,541

Applicant(s)

AKIMOTO ET AL

Examiner

Dr. Kailash C. Srivastava

Art Unit

1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 June 2005.  
2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,7-34,37-43,45-49,51,52,54,57-64,67,68,74-77,79 and 80 is/are pending in the application.  
4a) Of the above claim(s) 15-29,45-49,51,59-64,74-77,79 and 80 is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-2, 7-14, 30-34, 37-43, 52, 54, 57-58 and 67-68 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The Art Unit Location to which your application has been assigned at the USPTO is changed to Art Unit 1655. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Kailash C. Srivastava in Art Unit 1655.
2. Applicant's response and amendment filed 13 June 2005 to Office Action mailed 13 December 2004 is acknowledged and entered. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office action.
3. Examiner notes that in the remarks presented in the response filed 13 June 2005 in reply to the Office Action mailed 13 December 2004, applicants state that Claims 72-73 have been amended (See Remarks, Page 15, Lines 5 and 9; Page 16, Line 14) yet in Claim listings and in Remarks Page 16, Line 16 applicants state that Claims 71-73 have been cancelled. In response to this Office Action, applicants need to clearly state the status of Claims 72-73. Are they cancelled or are they amended? Applicants are reminded that once a Claim is cancelled the same claim with same Claim number cannot be re-instated in a subsequent response.

### **CLAIMS STATUS**

4. Claims 3-6, 35-36, 44, 50, 53, 69 and 78 stand cancelled. Claims 55-56, 65-66 and 70-73 are also been cancelled
5. Claims 15-29, 45-49, 51, 59-64, 74-77 and 79-80 stand withdrawn.
6. Claims 1-2, 14, 30-34, 38-39, 42-43, 54 and 67-68 have amended.
7. Claims 1-2, 7-14, 30-34, 37-43, 52, 54, 57-58 and 67-68 are pending and are examined on merits.

### **Objection To Claims**

8. Objections under 37 CFR §1.75 to Claims 2, 7-14, 34, 37-41 and 67-68 drawn as being a substantial duplicate to Claim 1 and to Claims 30-33 respectively in Office Action mailed 13 December 2004 is adhered to for the reasons of record at Pages 2-3, items 9-11 in the Office Action cited *supra*.

In response filed 13 June 2005 to the objection cited *supra* in the Office Action mailed 13 December 2004, applicants argue that since Claims 1 and 30-33 respectively have not been yet been found to be allowable, the objection is a future event and will be addressed when "such matters become actual objections to the" cited claims.

Examiner acknowledges applicants' above-cited response.

### ***Claim Rejections - 35 U.S.C. § 112***

#### ***Second Paragraph Rejections***

9. Pursuant to the amendments made, and arguments presented in applicant's response filed 13 June 2005, Examiner hereby withdraws rejections made under 35 U.S.C. § 112 ¶2 to Claims 1-2, 7-14, 30-34, 37-43, 52, 54-58 and 67-68 in Office Action mailed 13 December 2004.

#### ***Claim Rejections Under 35 U.S.C. § 102(b)***

10. Claims 1-2, 7, 11-14, 30, 34, 37, 41-42, 52, 54, 58 and 67-68 stand rejected under 35 U.S.C. § 102(b) as anticipated by Shinmen et al. (EP Application 0 276 982 A2) for the reasons of record at Page, item in the Office Action mailed 13 December 2004.

In response to the rejection under 35 U.S.C. § 102(b) cited *supra*, citing several case laws, applicants argue that the cited prior art reference "neither explicitly, nor inherently describes a mutant which extracellularly secretes an unsaturated fatty acid containing lipid vesicles" and thus, does not teach every element of the claimed invention in one single item of the prior art.

Applicants' arguments filed 13 June 2005 in regard to rejections made in the Office Action mailed 30 December 2004 have been carefully and fully considered but they are not persuasive. The rejections under 35 U.S.C. § 102(b) are adhered to for the reasons of record at pages 5-6, item 14 of the Office Action mailed 30 November 2004 and the additional reasons discussed *infra*.

Within the four corners of Claims 1-2, 7, 11-14, 30, 34, 37, 41-42, 52, 54, 58 and 67-68 a mutant microorganism that extracellularly secretes an unsaturated fatty acid containing lipid vesicles is claimed. Furthermore, Feit et al. (2003, J. Pat. Trade. Off. Soc., Vol. 85, No. 1, pages 5-21) teach three criteria for inherency. (1) The most important criterion is certainty. Citing *In re Tomlinson* and *In re Zierden*, Feit et al. state that certainty is established when the reference process necessarily **results** in the claimed process as opposed to a **possibility**. (2) The second criterion is chronology; it will always happen. Feit et al. state that the chronological test is forward

chronology. Citing *Eli Lilly and Co. v Barr Laboratories, Inc.*, Feit et al. argue that the claimed result must always be obtained based upon the prior art method. 3) The third criterion is the legal standard. Feit et al., citing *Continental Can*, state that the legal standard is whether the missing descriptive material would be so recognized by a person of ordinary skill in the art as necessarily present in the thing.

With reference to anticipation rejections cited supra, the first of Feit et al's teachings is met because Shinmen et al. teach a *Mortierella* microorganism that produces lipids when cultured in a liquid or on a solid medium (Page 2, Lines 16-43; Page 3, Line 58; Page 7 Lines 33-65). Shinmen et al. further teach that said lipid comprising vesicles have the same lipid/fatty acid composition as is instantly claimed. Thus, the second and third teachings from Feit et al. logically follow because the first teaching is met by the cited prior art reference.

### ***Claim Rejections Under 35 U.S.C. § 103(a)***

11. Claims 1-2, 7, 11-14, 30, 34, 37, 41-42, 52, 54, 58 and 67-68 stand rejected under 35 U.S.C. § 103 (a) as being Obvious over Shinmen et al. (EP Application 0 276 982 A2)

In response to the rejection under 35 U.S.C. § 103(a) cited *supra*, applicants argue that the cited prior art reference does not make of record a *prima facie* case of obviousness because it does not teach or suggest a mutant which extracellularly secretes lipid vesicles, wherein said vesicles contain unsaturated fatty acids.

Applicants' arguments filed 13 June 2005 in regard to rejections made in the Office Action mailed 30 December 2004 have been carefully and fully considered but they are not persuasive. The rejections under 35 U.S.C. § 103(a) are adhered to for the reasons of record at Pages 6-7, item 16 in the Office Action mailed 13 December 2004 and the additional reasons discussed in item 7 *supra*.

12. In response to applicants' argument that there is no suggestion in the prior art reference for the claimed invention, the examiner recognizes that obviousness can only be established by modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, those reasons are cited at pages 6-7, item 16 in the Office Action mailed 30 December 2004 and the additional reasons discussed in item 7 *supra*. Furthermore, a rejection under 35 U.S.C. § 103 (a) is

also based upon a reason or technical consideration that is different from that which resulted in the claimed invention.

### CONCLUSION

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

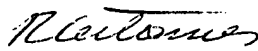
14. For the aforementioned reasons, no claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:30 A.M. to 6:00 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Bruce Campell, can be reached on (571)-272-0974 Monday through Friday 8:00 A.M. to 4:30 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). Alternatively, status inquiries should be directed to the receptionist whose telephone number is (703) 308-0196.

  
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RALPH GITOMER  
PRIMARY EXAMINER  
GROUP 1200

29 August 2005